Welcome to the COVID-19 Testing Decision Making Tool

Use this tool to help guide your decision on the type of COVID-19 test that may be right for you. This tool also provides information to enhance awareness and rationale in support of your decision.

To tailor this experience to your needs, please choose the description that best applies to you.

I am a:

Clinician or medical staff

Decision maker at a business/university

Member of the public

COVID-19 Testing Decision Making Tool

You chose "Clinician or medical staff."

What do you need to do?

Detect antibodies ?

Conduct medical diagnostic ?

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COVID-19 Testing Decision Making Tool

You chose "Decision maker for a business or university."

What do you need to do? ?

Determine if my employees or students were **previously** infected with COVID-19. ?

Determine if my employees or students are **currently** infected with COVID-19. ?

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COVID-19 Testing Decision Making Tool

You chose "Decision maker for a business or university."

What do you need to do?

Determine if my employees or students were **previously** infected with COVID-19.

Determine if my employees or students are **currently** infected with COVID-19.

Detecting antibodies, which are made by a person in response to infection, is an indirect test. This can provide insight into previous infections.

A medical diagnostic is a procedure or test to identify a condition, disease, or illness. In this case, to determine if an individual has COVID-19.

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COVID-19 Testing Decision Making Tool

You chose "Member of the public."

What are you interested in learning

Determine if I **previously** had COVID-19. ?

Determine if I **currently** have COVID-19. ?

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COVID-19 Testing Decision Making Tool

You chose "Member of the public."

What are you interested in learning about?

Determine if I **previously** had COVID-19.

Determine if I **currently** have COVID-19.

If I previously had COVID-19, I would have **antibodies** (made by person in response to an infection) and would need to detect these antibodies with a **serology** test.

If I currently have COVID-19, I would have the **virus** present in my body, and I would need to directly detect the virus with a **diagnostic** test.

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COVID-19 Testing Decision Making Tool

Antibodies

You chose "Detect antibodies or determine if someone was <u>previously</u> infected with COVID-19."

ANSWER:

You will need to have a **serology** test.

An antibody test looks for the presence of antibodies, which are specific proteins made in response to infections. Antibodies are detected in the blood of people who are tested after infection.

Do you have internal health/medical services, such as student health services?

✔ Yes ✖ No

These facilities must be operating under a CLIA Certificate of Waiver.

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COVID-19 Testing Decision Making Tool

Antibodies

You chose "Determine if I previously had COVID-19."

ANSWER:

A serology test detects antibodies which are produced by your body in response to an infection.

You will need to have a **serology** test. Work with your health care provider to discuss your risk factors, organize any records or referrals needed for testing, and locate a testing site nearby.

For your awareness, there are multiple types of serology tests:

- Point-of-care (POC), otherwise known as Lateral Flow Assays (LFA). These are performed with a small drop of blood and can return results in 10-15 minutes. For more information about POC/LFA tests, click here.
- ELISA tests are more accurate but can take more time. For more infomation about these types of tests, click here

Many states are offering drive-thru testing sites. For more information, visit your state's health department website. If possible, call ahead to confirm testing days and hours.

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COVID-19 Testing Decision Making Tool

Antibodies | General public POC/LFA

There are a number of **Point-of-care/Lateral Flow Assay (POC/LFA)** serology tests availalbe, see table below.

POC/LFA serological tests with Food and Drug Administration (FDA) Emergency Use Authorization (EUA):

Test Manufacturer	Test Name
Cellex Inc.	qSARS-CoV-2 IgG/IgM Rapid Test
Chembio Diagnostic System Inc	DPP COVID-19 IgM/IgG System
Autobio Diagnostics Co. Ltd.	Anti-SARS-CoV-2 Rapid Test
Healgen Scientific LLC	COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)

Click here to learn more about testing parameters of these tests

Click here once you obtain results from your serology test to learn more

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COVID-19 Testing Decision Making Tool

Antibodies | General public

ELISA (Enzyme-Linked ImmunoSorbent Assay) testing is a common laboratory-based serology test that is used to detect antibodies in blood. ELISA tests often require more time for results to be returned. Your testing location may send off your sample to be tested in a commercial lab. Work with your healthcare provider to collect a sample for testing or locate a commercial lab that conducts serology testing.

A list of commercial labs and their websites can be found here:

Example commercial labs that conduct serology tests:

- Ambry Genetics
- ARUP Laboratories
- Laboratory Corporation of America
- Quest Diagnostics

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COVID-19 Testing Decision Making Tool

Antibodies | No Health Services

You chose "No" to having a health/medical services.

ANSWER:

Work with approved lab to conduct indirect **ELISA** or other laboratory-based serology tests.

Additionally, consider using an **at-home collection** kit.

Will require licensed healthcare provider to place orders and review results with patients.

A list of commercial labs and their websites can be found here:

Example commercial labs that conduct serology tests:

- Ambry Genetics
- ARUP Laboratories
- Laboratory Corporation of America
- Quest Diagnostics

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COVID-19 Testing Decision Making Tool

Antibodies

Has Health Services

You chose "Yes" to having a health/medical services.

ANSWER:

Use indirect **Point-of-care/Lateral Flow Assay (POC/LFA)** serology test.

Ensure the services have proper PPE, necessary materials, and protocols in place.

POC/LFA serological tests with Food and Drug Administration (FDA) Emergency Use Authorization (EUA):

Test Manufacturer	Test Name
Cellex Inc.	qSARS-CoV-2 IgG/IgM Rapid Test
Chembio Diagnostic System Inc	DPP COVID-19 IgM/IgG System
Autobio Diagnostics Co. Ltd.	Anti-SARS-CoV-2 Rapid Test
Healgen Scientific LLC	COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)

Click here to learn more about testing parameters of these tests

Click here once you obtain results from your serology test to learn more

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COVID-19 Testing Decision Making Tool

Antibodies | Has Health Services | Test Parameters

Test Parameters of POC/LFA Serology Tests

Test Manufacturer	Test Name	Sensitivity ?	Specificity ?
Cellex Inc.	qSARS-CoV-2 IgG/IgM Rapid Test	93.8% (95% CI 88.2%-96.8%)	96.0% (95% CI 92.8%- 97.8%)
Chembio Diagnostic System Inc	DPP COVID-19 IgM/IgG System	93.5% (95% CI 79.3-98.2%)	94.4% (95% CI 88.9%-97.3%)
Autobio Diagnostics Co. Ltd.	Anti-SARS-CoV-2 Rapid Test	IgM 95.7% (95% CI 92.8%-97.5%) IgG 99.0% (95% CI 97.1%-99.7%)	IgM 99.7% (95% CI 98.2%-99.9%) IgG 99.4% (95% CI 97.7%-99.8%)
Healgen Scientific LLC	COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)	100 (95% CI 88.7%-100%)	97.5% (95% CI 91.3%-99.3%)

Click here to learn more about Postive and Negative Predictive Values

Click here once you obtain results from your serology test to learn more

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COVID-19 Testing Decision Making Tool

Antibodies | Has Health Services | Test Parameters

Test Parameters of Medical Diagnostics

Sensitivity:

Sensitivity measures how often a test correctly generates a positive result for people who have the condition that's being tested for (also known as the "true positive" rate).

Specificity:

Specificity measures a test's ability to correctly generate a negative result for people who don't have the condition that's being tested for (also known as the "true negative" rate).

Click here to learn more about Postive and Negative Predictive Values

Click here once you obtain results from your serology test to learn more

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COVID-19 Testing Decision Making Tool

Antibodies | Has Health Services | Test Parameters | PPV and NPV

Positive and Negative Predictive Values (PPV and NPV)

Using an assumption about the percentage of individuals in the population who have antibodies to SARS-CoV-2 (which is called "prevalence" in these calculations). Every test returns some false positive and false negative results. The PPV and NPV help those who are interpreting these tests understand, given how prevalent individuals with antibodies are in a population, how likely it is that a person who receives a positive result from a test truly does have antibodies to SARS-CoV-2.

For more information about this, visit FDA's website about testing parameters.

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COVID-19 Testing Decision Making Tool

Antibodies | Serology Test Results

Your employee or student recieved results from their serology test.

Negative Serology Test Result:

A negative serology test in an indication that one **MAY** not have had COVID-19 in the past; however, it is not conclusive, there are other external factors that could provide a negative test result:

- False-negative/accuracy of test
- Too early and antibodies have not generated yet
- Not enough antibodies are generated and level is below detectable levels

Consider retesting to verify results.

Positive Serology Test Result:

A positive serology test is an indication that one **MAY** have had COVID-19 recently. Ask your employee or student to alert their health care provider to learn more about what to do with a previous infection.

However, there are other external factors that could provide a postive test result. It could be a false-positive result. Consider retesting to verify results.

Does this give me immunity?

Click here to learn more about specificity of these tests

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COVID-19 Testing Decision Making Tool

Antibodies | Serology Test Results

You received results from your serology test.

Negative Serology Test Result:

A negative serology test in an indication that you **MAY** not have had COVID-19 in the past, however it is not conclusive, there are other external factors that could provide a negative test result:

- False-negative/accuracy of test
- Too early and antibodies have not generated yet
- Not enough antibodies are generated and level is below detectable levels

Consider retesting to verify results.

Positive Serology Test Result:

A positive serology test is an indication that you **MAY** have had COVID-19 recently. Alert your health care provider to learn more about what to do if you were previously infected.

However, there are other external factors that could provide a postive test result, it could be a false-positive result. Consider retesting to verify results.

Does this give me immunity?

Click here to learn more about specificity of these tests

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COVID-19 Testing Decision Making Tool

Antibodies | Serology Test Results | Positive Serology Test Results

You received a "Positive" result from your serology test and want to know what it means.

ANSWER:

Conduct **neutralization** test.

This test needs to be conducted in a research lab as no commercial neutralization tests are available at this time.

Negative Neutralization Test Result:

No immunity, or it may be too early to obtain neutralization activity.

Positive Neutralization Test Result:

At this time, a positive neutralization test has not been linked to long term immunity. Research is still ongoing in this space. Immunity cannot be confirmed at this time.

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COVID-19 Testing Decision Making Tool

Diagnostics

You chose "Conduct medical diagnostics or determine if my employess or students are currently infected with COVID-19."

Do you have internal health/medical services?

✔ Yes ✖ No

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COVID-19 Testing Decision Making Tool

Antibodies

You chose "Determine if I currently have COVID-19."

ANSWER:

You will need a **medical diagnostic** test. Work with your healthcare provider to obtain a referral for a test.

A test to directly detect the virus is needed.

There are multiple types of tests that can be performed for the general public:

- **RT-PCR** done at a physician's office, local pharmacy, or drive-thru testing. Click here for more information.
- **At-home collection** kits are also available. Click here for more info.
- **Next Generation Sequencing (NGS)** is another option, but would take longer for the results to be returned. Click here for more details about NGS options.

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COVID-19 Testing Decision Making Tool

Antibodies

You chose "Determine if I currently have COVID-19."

ANSWER:

You will need a **medical diagnostic** test. Work with your healthcare provider to obtain a referral for a test.

A test to directly detect the virus is needed.

There are multiple types of tests that can be performed for the general public:

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- **At-home collection** kits are also available. Click here for more info.
- **Next Generation Sequencing (NGS)** is another option, but would take longer for the results to be returned. Click here for more details about NGS options.

FYI:
RT-PCR is gold standard for directly detecting viral pathogen genomic pieces.

FYI:
Next-generation sequencing (NGS) analyzes the entire viral genome, determines variations and antigenic shift of the virus.

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Antibodies

You chose want to learn more about RT-PCR options.

Real time reverse transcription polymerase chain reaction (often referred to as **RT-PCR**) is a testing technique used detect targeted genetic materials. A sample is collected from a body part known to harbor the virus (like the nose or throat) and then treated with chemical solutions to extract RNA. That RNA will then be reverse transcribed to DNA by the addition of enzymes and placed into the RT-PCR machine. The machine will amplify the viral DNA, making it more easily detectable.

Sample collection can be done at a healthcare facility, local pharmacy, or drive-thru testing site.

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COVID-19 Testing Decision Making Tool

Antibodies

You chose want to learn more about at-home-collection options.

At-home collection kits are available and allow for the collection of a nasal sample in the comfort of your own home. Commercial laboratories will send you an at-home kit to collect your nasal swab sample, and all you need to do is ship it back to the lab.

These do not test for immunity or antibodies, but can be used to test if you have an active infection at the time of completing a nasal swab included in the kit. Companies that have at-home testing kits at this time include:

- Pixel by LabCorp: Website
- Everlywell, Inc.: Website
- Vault Health/Rutgers University.: Website

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Antibodies

You chose want to learn more about NGS options.

Next Generation Sequencing (NGS) is a more extensive test that requires sequencing of the entire genome of the SARS-CoV-2 virus, and comparing sequencing results over time can help scientists understand if and how viruses mutate. Results can be returned to patients in 24 hours.

- Fulgent Genetics COVID-19 NGS test: Website
- Ginkgo Bioworks: Website

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COVID-19 Testing Decision Making Tool

Diagnostics | Health Services

You chose "Yes" to having a health/medical services.

Is your internal health/medical services a CLIA-waived lab? ?

Yes | No | Don't know

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COVID-19 Testing Decision Making Tool

Diagnostics | Health Services | CLIA-waived

You chose "Yes" to CLIA-waived lab.

ANSWER:

Conduct a **Point-of-care** test by collecting nasal or oral samples and running a test at your medical or health services facility. These tests require specialized equipment. Visit the external, commercial websites below for more information.

Ensure the services have proper PPE, necessary materials, and protocols in place.

Point-of-care tests include:

Antigen-based

- Quidel Corporation's Sofia 2 SARS Antigen FIA: Website

RNA-based

- Abbott Diagnostics' ID NOW COVID-19: Website

Click here once you obtain results from your diagnostic test to learn more

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COVID-19 Testing Decision Making Tool

Diagnostics | Health Services | No CLIA-waived

You chose "No" to CLIA-waived lab.

ANSWER:

Set up an account with a commercial lab to conduct **RT-PCR** or **Next-generation sequencing (NGS)**.

Additionally, consider using an **at-home collection** kit to collect samples for submission to commercial lab. ?

A list of commercial labs and their website can be found here:

Example commercial labs that conduct serology tests:

- Ambry Genetics
- ARUP Laboratories
- Laboratory Corporation of America
- Quest Diagnostics

Click here once you obtain results from your diagnostic test to learn more

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COVID-19 Testing Decision Making Tool

☑ Diagnostics ☑ Health Services ☑ No CLIA-waived

You chose "No" to CLIA-waived lab.

ANSWER:

Setup an account with a commercial lab to conduct **RT-PCR** or **Next-generation sequencing (NGS)**.

Additionally, consider using an **at-home collection** kit to collect samples for submission to commercial lab.

RT-PCR is gold standard for directly detecting parts of the viral pathogen genome.

Next-generation sequencing analyzes the entire viral genome, determines variations and antigenic shift.

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- Quest Diagnostics

Click here once you obtain results from your diagnostic test to learn more

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Diagnostics | Health Services

COVID-19 Testing Decision Making Tool

☑ Diagnostics ☑ Health Services

You chose "No" to having a health/medical services.

ANSWER:

Work with approved lab to conduct medical diagnostic tests or consult local medical staff for a recommended path forward.

There are two types of testing:
RNA or Antigen ?

Additionally, consider promoting the use of a **at-home-testing** kits that will allow your employees or students to collect a nasal or oral sample from the comfort of their own home.

At-home-testing kits include:

- Everlywell, Inc.'s COVID-19 Test Home Collection Kit: Website
- Pixel by LabCorp: Website

Click here once you obtain results from your diagnostic test to learn more

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COVID-19 Testing Decision Making Tool

Diagnostics | Health Services

You chose "No" to having a health/medical services.

ANSWER:

Work with approved lab to conduct medical diagnostic tests or consult local medical staff for a recommended path forward.

Viral antigen is a protein, usually structural, component of a virus.

There are two types of testing:
RNA or Antigen

Viral RNA is the genomic component of the virus.

Additionally, consider promoting the use of a **at-home-testing** kits that will allow your employees or students to collect a nasal or oral sample from the comfort of their own home.

At-home-testing kits include:

- Everlywell, Inc.'s COVID-19 Test Home Collection Kit: Website
- Pixel by LabCorp: Website

Click here once you obtain results from your diagnostic test to learn more

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Diagnostics

You want to know more about CLIA Labs.

CLIA, Clinical Laboratory Improvement Amendments, Laboratories meet requirements to perform different types of diagnostic tests tests and are approved to conduct COVID-19 testing.

Find more information about CLIA labs here.
(this link will take you to an external website)

COVID-19 Testing Decision Making Tool

Diagnostics | Test Results

You received results from your diagnostic test.

Negative Result:

This may mean:

- You are not infected
- Virus may not present in test specimens
- The test returned false-negative even though you are infected
- If you have symptoms, proceed with cuation, a negative result may require re-testing

Positive Result:

Report to local public health and provide guidance to employee on next steps.

Do you want to know previous exposure?

Does this give me immunity?

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